REMARKS

Upon entry of the foregoing amendments, claims 2 to 19 will be pending in the above-identified patent application. Claims 2, 4, and 7 to 19 have been amended. Claim 1 has been canceled, without prejudice.

The Action includes rejections under 35 U.S.C. §§ 101 (Double Patenting), 102(b), 103(a), and 112, second paragraph. In view of the foregoing amendments and the following remarks, reconsideration and withdrawal of the rejections are respectfully requested.

Discussion of the Rejection Under 35 U.S.C. § 101 (Double Patenting)

Claims 1 to 19 have been provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the "same invention" as that claimed in copending application Serial No. 10/644,109 ("the 109 application"). Applicants traverse respectfully this rejection.

In the first instance, claim 1, the only claim that recites potentially overlapping subject matter with the 109 application, has been canceled, without prejudice.

Moreover, the claims of the present application are different from those of the 109 application. In this regard, the claims of the present application define a "method for ***treating*** a motoneuron disease in a patient by increasing the survival and/or growth of motoneurons in said patient" (*see, e.g.*, claim 2) (emphasis added). In contrast, the claims of the 109 application define a "method for ***preventing***" a motoneuron disease (*see, e.g.*, claim 2 of the 109 application) (emphasis added). Indeed, although the claimed low molecular weight heparins may act to increase the survival and/or growth of motoneurons, ***preventing*** and ***treating*** a motoneuron disease are different actions. Accordingly, reconsideration and withdrawal of the provisional double patenting rejection are requested respectfully.

Discussion of the Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1 to 19 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. With regard to claims 1 to 19, the Action alleges that the term "exposing" is unclear (Action at 3). Although Applicants respectfully disagree that the term "exposing" is unclear, Applicants submit that, in view of the foregoing amendments, this rejection is now moot.

With regard to claims 18 and 19, the Action alleges that the alphanumeric notations for the heparins are unclear (id.). Applicants note respectfully that documentation was submitted in

a Reply dated June 18, 2004, in co-pending patent application Serial No. 10/644,109 to establish that such alphanumeric notations are well known and understood by those of ordinary skill in the art. Applicants further note that, in view of such evidence, the Examiner withdrew the rejection in the Office Action dated September 24, 2004, i.e., the Office Action that was responsive to the June 18, 2004 Reply in connection with co-pending patent application Serial No. 10/644,109. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are requested respectfully.

Discussion of the Rejection Under 35 U.S.C. § 102(b)

Claim 2 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by published PCT patent application No. WO 94/18988 to VonArnim ("the 988 application"). Applicants traverse respectfully this rejection as the 988 application does not disclose each and every element of Applicant's claimed invention as defined by claim 2.

Claim 2 defines a "method for treating a ***motoneuron disease*** in a patient by increasing the survival and/or growth of motoneurons in said patient" comprising administering to the patient a pharmaceutically effective amount of a low molecular weight heparin. Significantly, the 988 application does ***not*** disclose or suggest treatment of motoneuron diseases.

In this regard, the 988 application teaches administrating heparin for the treatment of ***inflammatory diseases*** and ***immunological diseases*** such as, for example, multiple sclerosis. The Action, however, asserts that the 988 application anticipates claim 2 because the disease "multiple sclerosis is within the scope of motoneuron diseases" (Action at 3). Such statement is demonstrably false as multiple sclerosis is ***not*** a motoneuron disease.

Multiple sclerosis (MS) is a demyelinating disease. A demyelinating disease is characterized by patchy destruction of myelin sheaths in the central nervous system (lesions) accompanied by an inflammatory response (*see, e.g.*, Harrison's Principles of Internal Medicine, Twelfth Edition at pages 2038-2044 (1991); Exhibit A). While the cause of MS is not known with certainty, it is suspected that autoimmunity is likely implicated and, accordingly, MS is often referred to as an ***autoimmune or an immunological disease*** (id. at 2038). In further support, attached hereto as Exhibit B is a 1998 publication entitled "Understanding Autoimmune Diseases," NIH Publication No. 98-4273 ("the NIH publication"). The NIH publication at page 3 clearly shows that multiple sclerosis is an example of an autoimmune disease.

A motoneron disease, in contrast, is a disease characterized by progressive degeneration of motor neurons, *i.e.*, neurons that control the behavior of muscles (*see, e.g.*, the GAPS Index Glossary attached hereto as Exhibit C). Indeed, one of ordinary skill in the art understands that a demyelinating disease (or autoimmune disease) and a motoneuron disease ***are different***. For example, the Abstract of the 1996 publication entitled "Investigation of corticospinal dysfunction in multiple sclerosis and sysmotoneuron diseases using motor evoked potentials" by Gomez-Fernandez et al. (Exhibit D) clearly evidences that the skilled artisan considers multiple sclerosis to be ***separate*** from and, thus, not included in the same class as motoneuron disease:

> [t]he introduction of motor evoked potentials (MEP) into neurological practice has been very useful in the study of motor disorders, especially in patients with ***motor neurone diseases*** (MND) ***and multiple sclerosis***

(emphasis added). Referring back to Exhibit C, "motor neurone disease" is synonymous with "motoneuron disease."

Although no supporting evidence was presented in the present case, the Examiner, in an Action dated September 24, 2004 in corresponding related case 10/644,109 (co-pending), appears to base the conclusion that MS is a motoneuron disease on a statement from an internet publication by the American Speech-Language-Hearing Association entitled "Amyotrophic Lateral Sclerosis" that appears to categorize MS as a "motor neuron disorder." Applicants submit respectfully that, in view of the above evidence, the statement relied upon by the Action is, at best, suspect. Indeed, the medical literature classifies MS as a demyelinating disease and ***not*** a motoneuron disease. Thus, since multiple sclerosis is not a motoneuron disease, the rejection for alleged anticipation in view of the 988 application is improper and should be withdrawn. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ.2d 1051, 1053 (Fed. Cir. 1987) ("[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

Discussion of the Rejection Under 35 U.S.C. § 103(a)

Claims 1 to 19 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over PCT published patent application No. WO 91/06303 to Snow et al. ("the 303 application"). Applicants respectfully traverse this rejection as the 303 application does not provide the required art-suggested motivation for modifying its teaching in such a way as

to obtain Applicants' claimed invention. *In re Napier*, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995).

Applicants' claimed invention defines a method for treating a motoneuron disease in a patient by increasing the survival and/or growth of motoneurons in said patient comprising administering to the patient a pharmaceutically effective amount of a low molecular weight heparin (*see, e.g.*, claim 2). In contrast, the 303 application does not teach or suggest that heparin – whether low or high in molecular weight – can be used to ***increase*** the growth and/or survival rate of motoneurons.

The 303 application teaches that the disclosed polysaccharides such as, for example, heparin, ***inhibit*** nerve cell growth, ***not promote such growth*** as is defined by Applicants' claimed invention (*see, e.g.*, Abstract; page 8, lines 9 to 21 ("[s]upport of neurite outgrowth by fibronection was significantly ***reduced*** by the addition of heparin to a HEMA/fibronection gel") (emphasis added); page 9, lines 22 to 24 ("[p]resence of these glycans [which includes heparin] ***inhibits neurite outgrowth*** even in the presence of nerve growth-promoting factors such as laminin and NCAM.") (emphasis added); and page 23, line 6 to page 24, line 28).

To the extent that the 303 application teaches that heparin can be used in a composition to ***promote*** nerve cell growth, the 303 application teaches that inhibitory effects of heparin need to be ***neutralized*** by the presence of antagonists (page 10, lines 15 to 33). Thus, the 303 application teaches the use of compounds that are inhibitory of heparin and ***teaches against*** the use of heparin alone and compounds that are mimetics (mimics) of heparin to promote nerve cell growth. Indeed, such teachings are ***incapable*** of providing the required art-suggested motivation for modifying the 303 application's teachings in such a way as to obtain Applicants' claimed invention, *i.e.*, the use of a low molecular weight heparin as a nerve cell promoter. *In re Napier*, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

Conclusion

The foregoing is submitted as a full and complete response to the Communication mailed on May 5, 2005 and the Action mailed on August 11, 2004, and the allowance of all claims is respectfully requested. If there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney at (908) 231-3410.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

Dated: June 1, 2005

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